**IDSA Headquarters**
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
**TEL:** (703) 299-0200
**FAX:** (703) 299-0204
**EMAIL ADDRESS:**
info@idsociety.org
**WEBSITE:**
www.idsociety.org

# IDSA
Infectious Diseases Society of America

June 30, 2009

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, National Institutes of Health
31 Center Drive, Room 7A03
Bethesda, MD 20892-2520

Dear Dr. Fauci:

The Infectious Diseases Society of America (IDSA), which represents more than 8,600 infectious diseases physicians and scientists, has become increasingly concerned about the effects of regulatory burden on the conduct of much-needed translational research. Evidence from carefully performed studies on research oversight has shown that the current system is unduly delaying research (1, 2), resulting in increased costs (3, 4) and an inability to complete some valuable projects (1). IDSA is in complete agreement with the need for independent and careful review of research involving humans, but we are equally convinced that our patients cannot afford the delays and unnecessary redundancies that afflict the current research oversight system. We are writing to urge your support for two related efforts that can improve multicenter studies including: 1) the creation of a central institutional review board (IRB) by the National Institute of Allergy and Infectious Diseases (NIAID) and 2) the creation of incentives to local institutions to use the central IRB.

One of the unnecessary redundancies in research oversight is the duplicative review of multicenter studies (many of which are sponsored through the NIAID) by the local IRBs of each participating site. Careful, quantitative research has shown that such duplicative review delays study initiation (2, 5, 6), requires substantial resources from local investigators and IRBs (2, 3) and does not improve the protocol and informed consent documents. In fact, several studies have shown that informed consent documents become longer and more difficult to read during the process of local review and that mistakes are inserted into some consent documents (2, 7, 8).

In order to improve the research oversight system for NIAID-sponsored multicenter projects, we believe that a system developed by the National Cancer Institute (NCI) can be used as a model (9). Two central panels convened by the NCI (one for studies among adults, the other for studies among children) review proposed Phase 2 and 3 NCI-sponsored multicenter studies. Once approved, local institutions can cede oversight of a specific study to the NCI central review board, thus avoiding duplicative review. This process has been approved and in fact, recommended by the Office for Human Research Protection (OHRP) and the U.S. Food and Drug Administration (FDA). NCI central IRBs are increasingly being accepted by local IRBs around the United States. To date,

more than 600 local IRBs have registered with the NCI central IRB, and they are increasingly accepting its review (10). This results in both improved efficiency for important trials for the prevention and treatment of cancer and, in all likelihood, improved communication with research participants.

We urge NIAID to follow the NCI model and create central IRBs for adult and pediatric multicenter studies of infectious diseases. NCI has made a considerable investment in creating its central IRB panels, but in so doing that Institute has defined a process that should make the creation of central IRBs by other Institutes less expensive and less time-consuming. Years of working with NCI central IRBs has paved the way for acceptance of an NIAID central review panel by local IRBs. In addition, NCI has created an on-line system that fosters acceptance and use of the central review process. This system should be easily adaptable by other Institutes. Other federal agencies, including the Veteran's Administration, the Department of Energy and the Centers for Disease Control and Prevention (CDC), also have initiated central IRB models (11, 12).

Despite the success of the NCI central IRB model, there is still reluctance on the part of some local IRBs to take advantage of central review (13, 14). Therefore, we propose that NIAID also develop incentives to encourage local institutions to accept central review. An incentive that might increase the willingness of local institutions to use central review is to provide an advantage in the peer-review process to proposals that would use central review. A recent proposal for clinical trials sites from CDC's Division of Tuberculosis Elimination required applicants to document the duration of time necessary for review of recent clinical trials at their institution and notes that applicants who are willing to use central review will be preferred. Given the delays caused by the local review system (more than one year in some studies), such an incentive is a responsible way for the federal government to foster research productivity.

As an organization that advocates for clinical care and research, IDSA is devoted to assuring that needed research is being done and that research participants are protected in the most robust fashion possible. We think that the two steps outlined above can improve the efficiency of research oversight and our ability to communicate with prospective research participants.

Sincerely,

Anne A Gershon

Anne A. Gershon, MD, FIDSA
IDSA President

References

1. **Ness RB.** Influence of the HIPAA Privacy Rule on health research. *Jama*. 2007;298(18):2164-70.
2. **Burman W, Breese P, Weis S, Bock N, Bernardo J, Vernon A.** The effects of local review on informed consent documents from a multicenter clinical trials consortium. *Control Clin Trials*. 2003;24(3):245-55.
3. **Humphreys K, Trafton J, Wagner TH.** The cost of institutional review board procedures in multicenter observational research. *Ann Intern Med*. 2003;139(1):77.
4. **Wolf MS, Bennett CL.** Local perspective of the impact of the HIPAA privacy rule on research. *Cancer*. 2006;106(2):474-9.
5. **McWilliams R, Hoover-Fong J, Hamosh A, Beck S, Beaty T, Cutting G.** Problematic variation in local institutional review of a multicenter genetic epidemiology study. *Jama*. 2003;290(3):360-6.
6. **Sherwood ML, Buchinsky FJ, Quigley MR, et al.** Unique challenges of obtaining regulatory approval for a multicenter protocol to study the genetics of RRP and suggested remedies. *Otolaryngol Head Neck Surg*. 2006;135(2):189-96.
7. **Silverman H, Hull SC, Sugarman J.** Variability among institutional review boards' decisions within the context of a multicenter trial. *Crit Care Med*. 2001;29(2):235-41.
8. **Paasche-Orlow MK, Taylor HA, Brancati FL.** Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med*. 2003;348(8):721-6.
9. **Christian MC, Goldberg JL, Killen J, et al.** A central institutional review board for multi-institutional trials. *N Engl J Med*. 2002;346(18):1405-8.
10. **Goldberg J.** NCI central IRB model. *Regulation of clinical research: improving the balance*. Washington, DC; 2008.
11. **Veteran's Health Administration.** VA Central Institutional Review Board. 2008. Accessed at http://www.research.va.gov/programs/pride/cirb/default.cfm on 4 November 2008.
12. **Department of Energy.** DOE-Wide Central IRB Review of Beryllium Research. Accessed at http://humansubjects.energy.gov/worker-studies/be-irb.htm on 4 November 2008.
13. **McNeil C.** Central IRBs: why are some institutions reluctant to sign on? *J Natl Cancer Inst*. 2005;97(13):953-5.
14. **Loh ED, Meyer RE.** Medical Schools' Attitudes and Perceptions Regarding the Use of Central Institutional Review Boards. *Acad Med*. 2004;79(7):644-651.